Randomized Trial

Does Coadministration of Transforaminal Epidural Steroid Injection with Sedation Improve Patient Satisfaction? A Prospective Randomized Clinical Study

Savas Sencan, MD, Ipek Saadet Edipoglu, MD, Serhad Bilim, MD, and Osman Hakan Gunduz, MD

From: Department of Physical Medicine and Rehabilitation, Division of Pain Medicine, Faculty of Medicine, Marmara University, Istanbul, Turkey

Address Correspondence: Ipek Saadet Edipoglu, MD Marmara Üniversitesi Tıp Fakültesi Pendik Eğitim ve Araştırma Hastanesi Ağrı Bilim Dalı Fevzi Çakmak Mahallesi, Muhsin Yazıcıoğlu Cd No:10, 34899 Pendik/ İstanbul, Turkey
E-mail: dripeks@yahoo.com

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Background: Transforaminal epidural steroid injection (TFESI) can be administered with or without sedation in clinical practice.

Objectives: The aim of this study was to compare both procedures in terms of patient and physician satisfaction, preoperative anxiety level, procedural pain level, and complications.

Study Design: A prospective randomized trial.

Setting: A university hospital interventional pain management center.

Methods: The study included patients scheduled for single-level unilateral TFESI. The patients were randomized into 2 groups. The first group underwent TFESI without sedation, whereas the second group underwent TFESI with sedation. The Likert scale was used to determine the patient and physician satisfaction, and the Numeric Rating Scale (NRS-11) was used to determine the procedural pain level. Cases in which the procedure was to be repeated, the patient was questioned if they desired to undergo the procedure with the same technique.

Results: A total of 64 patients, (31 [48.4%] in the sedation group) were included. In the sedation group, the patient and physician satisfaction were significantly higher ($P = 0.0001$), the periprocedural NRS-11 scores were significantly lower ($P = 0.0001$), and the rate of desire to have the intervention with the same technique was higher ($P = 0.001$). After the regression analysis, we reported that there was a significant correlation between being in the sedation group and NRS-11 procedure scores, the desire to have the same technique, and patient and physician satisfaction (odds ratio [OR], 0.341; OR, 0.648; OR, 0.329; OR, 0.514; $P = 0.0001$).

Limitations: Both patients and physicians were unblinded.

Conclusions: Coadministration of TFESI with sedation improves patient and physician satisfaction. Additionally, the low periprocedural pain level results in patients' demand for the intervention to be performed with sedation in the event of repetition of the procedure.

Key words: Patient satisfaction, transforaminal epidural steroid injection, sedation, physician satisfaction

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One of the most important causes of lumbar radiculopathy, which is lumbar nerves being compressed, is lumbar disc herniation. Currently, numerous modalities are used in the treatment of lumbar disc herniation. Among these, short-term bed rest, medical treatment, physiotherapy and rehabilitation practices, psychotherapy, acupuncture, cryotherapy, epidural steroid injection, and surgical treatment are in the forefront (1). Epidural steroid injection, an interventional approach in patients who

cannot benefit from conservative treatment methods, is a very effective treatment method (2). Epidural steroid injections in the lumbar region can be performed by using 3 different methods; however, the most ideal approach among these appears to be transforaminal epidural steroid injection (TFESI), offering an effective treatment option in cases of radicular pain as it can reach the target area of direct pathology under the guidance of fluoroscopy (3,4).

Currently, TFESI is the most preferred treatment modality among the interventional pain management techniques with a continuing increase in practice rate. In clinical practice, these injections can be administered with or without sedation. The physician's preference, equipment condition, patient's preference, and comorbid diseases are considered in the decision of sedation. In the literature, there are a limited number of studies comparing factors, such as level of pain felt during the procedure, and satisfaction of patient and physician in respect of both administration types. These studies support the administrations without sedation and there are many methodological confounding issues including nonhomogeneity of types, localization and numbers of the procedures, inadequate number of patients undergoing sedation for comparison, retrospective design, sedation being administered only on a patient's request, and lack of specifications as to the depth of sedation. When the literature is reviewed in respect to the effects of sedation administration during the intervention on patient satisfaction in minimally invasive interventional procedures other than TFESI, the results are quite controversial. There are studies suggesting that coadministration with sedation are not effective on patient satisfaction, and many other studies suggest the contrary that they are very effective (5,6). Our hypothesis is that the sedation administered during TFESI will contribute positively to both patient and physician satisfaction.

Considering these results, the primary aim of our study is to compare the satisfaction of patients in the groups undergoing TFESI with or without sedation due to unilateral single nerve root involvement associated with lumbar disc herniation. The secondary aim of our study was to compare both groups in terms of satisfaction of treating physician, preprocedural anxiety level, periprocedural pain level, and complications.

Methods

Study Population

In this prospective randomized controlled study, patients diagnosed with radiculopathy due to lumbar disc herniation after clinical, physical examination and magnetic resonance imaging at the department of pain outpatient clinic were evaluated. The inclusion criteria of our study were determined as patients with American Society of Anesthesiologists grade I-III, aged 18 to 60 years, body mass index of < 40, unilateral single nerve root involvement due to lumbar disc hernia, and scheduled for TFESI with or without sedation. Patients with a known psychiatric disease, severe obstructive sleep apnea syndrome, cardiopulmonary disease that may lead to hemodynamic instability, history of previous surgery in the lumbar region, spinal disease (trauma/tumor), lumbar spinal stenosis, spondylolisthesis, polyneuropathy, amyotrophic lateral sclerosis and progressive neurologic disease, and those using an antiplatelet agent were excluded from the study. The Lee's Revised Cardiac Risk Index was used to determine high-risk cardiac diseases that may lead to hemodynamic instability; patients with coronary artery disease, recent myocardial infarction, congestive heart failure, history of cerebrovascular disease, moderate to severe aortic stenosis, and a creatinine value of > 2 mg/dL were excluded from the study. The patients to be included in the study were divided into 2 groups: sedation and nonsedation. The randomization method was used to allocate the patients to the treatment groups. The randomization was done using computer software.

The ethics committee approval for our study was obtained from the ethics committee of Marmara University with the decision number of 09.2018.589. Written and verbal informed consents were obtained from all patients who agreed to participate in the study.

Assessment Scales

All assessment scales used in the preoperative and postoperative follow-up period were administered by the same pain medicine fellow who was unaware of the patient groups. The preprocedural, periprocedural, and postprocedural second hour pain levels of the patients were questioned by the Numeric Rating Scale (NRS-11) and scored with numbers from 0 to 10 (no pain to worst pain imaginable). The patient and physician satisfaction were measured by the Likert scale (1 = very dissatisfied, 2 = dissatisfied, 3 = neither, 4 = satisfied, 5 = very satisfied). The procedure time (minutes) and the presence of complications were recorded. The periprocedural pain was accepted as the pain felt from the insertion of the needle for local anesthetic injection until the termination of the procedure by giving the

mixture of local anesthetic and steroid to the epidural area, and was questioned at the postprocedural second hour when the effect of sedative drugs completely wore off. The presence of complication was defined as the occurrence of undesired events in the periprocedural and postprocedural periods. In the event of repetition of the procedure, all patients in both groups were verbally questioned whether they would like to undergo the procedure with the same technique. The patients who were sedated were asked if they would accept the intervention with sedation again. The nonsedated group was asked if they would accept the intervention without sedation again. A 14-item Hospital Anxiety and Depression Scale (HADS), with a validated Turkish version, was used to determine the preoperative level of anxiety and depression (7).

Procedure Technique

TFESI

After clinical and radiologic evaluation, TFESI was performed by the pain specialist, with at least 10 years of experience, at the nerve root level to be treated. Before the procedure, all patients were informed in detail, and written and verbal consents were obtained for the procedure. The patient was placed in the prone position on the operating table. A pad was placed under the abdomen of the patient to make the spine straight and to obtain the image more clearly. To open the area to be treated and to visualize the facet joint and pars interarticularis better, the C-arm fluoroscopy device was positioned at an angle of 20° to 30° obliquely in the 10 to 15 craniocaudal direction toward the procedure area. The injection site was then sterilized by applying batticon solution 3 times and covered by a sterile drape. Local anesthetic agent (3 mL of 2% prilocaine) was injected into the cutaneous and subcutaneous tissue of the injection site. A 22- to 24-gauge 3.5-inch needle was advanced in the subpedicular area along the 6-o'clock direction under intermittent fluoroscopic visualization. When the epidural space was approached, whether the needle was in the subpedicular area was confirmed by taking a lateral image. After confirming the location of the needle, 1-2 mL of contrast medium was given to check whether the needle was in the epidural space (Fig. 1). After observing that the needle was in the epidural space and there was no vascularity, the mixture of corticosteroid, anesthetic agent, and physiological saline solution (80 mg of methylprednisolone, 1 mL of 0.5% bupivacaine, and 1 mL of physiological saline solution) was injected.

Sedation

In cases in which the TFESI procedure would be performed under sedation, sedation was administered by the same anesthesiologist with at least 10 years of experience in this field. The patients in the first group, who did not receive sedation, were not given any medication during the intervention. A bolus injection of 0.07 mg/kg midazolam and 2 µg/kg fentanyl was administered to the second group of patients for sedation after monitoring. The sedation depths were evaluated using the modified Observer's Assessment of Alertness/Sedation (MOAA/S) scale, and adjusted to an MOAA/S score of 3-4 (5 = responds readily to name spoken in normal tone [alert], 4 = lethargic response to name spoken in normal tone [mild sedation], 3 = responds only after slurring or name is called loudly and/or repeatedly [moderate sedation], 2 = responds only after mild prodding or shaking, 1 = does not respond to mild prodding or shaking).If the sedation dose was low, a rescue dose of 0.5 µg/kg of fentanyl and 0.02 mg/kg of midazolam was administered. This procedure was repeated until an MOAA/S score of 3-4 was achieved. The patients who developed deep sedation (MOAA/S score of 1-2) were excluded from the study, and no procedure was performed on these patients. The patients were observed for 2 hours postprocedure in the recovery room to monitor for any complications. At the end of this period, the patients underwent pain level questioning and examination, and were discharged with the recommendation of follow-up 3 weeks after discharge.

Statistical Analysis

The SPSS Statistics Version 21.0 software (IBM Corporation, Armonk, NY) was used for the statistical analyses. Descriptive statistical methods (mean, standard deviation, frequency, and rate) were used while evaluating the study data. The Mann-Whitney U test was used to compare the non-normally distributed quantitative data between the groups, and the Student t test was used to compare the qualitative data. The correlation between the patient groups, NRS-11 scores, and satisfaction levels were evaluated by multivariate logistic regression analysis. The Hosmer-Lemeshow test was used for the logistic regression model. Significance was evaluated at $P < 0.05$. The Power and Sample Size Software Version 3.1.2 (Vanderbilt Biostatistics, Nashville, TN) was used for the analysis of patient number. At least 63 patients were required for α of 0.05 and a power of 0.80 when we could foresee a 20% change in the NRS-11 scale. We calculated a total of 76 patients to

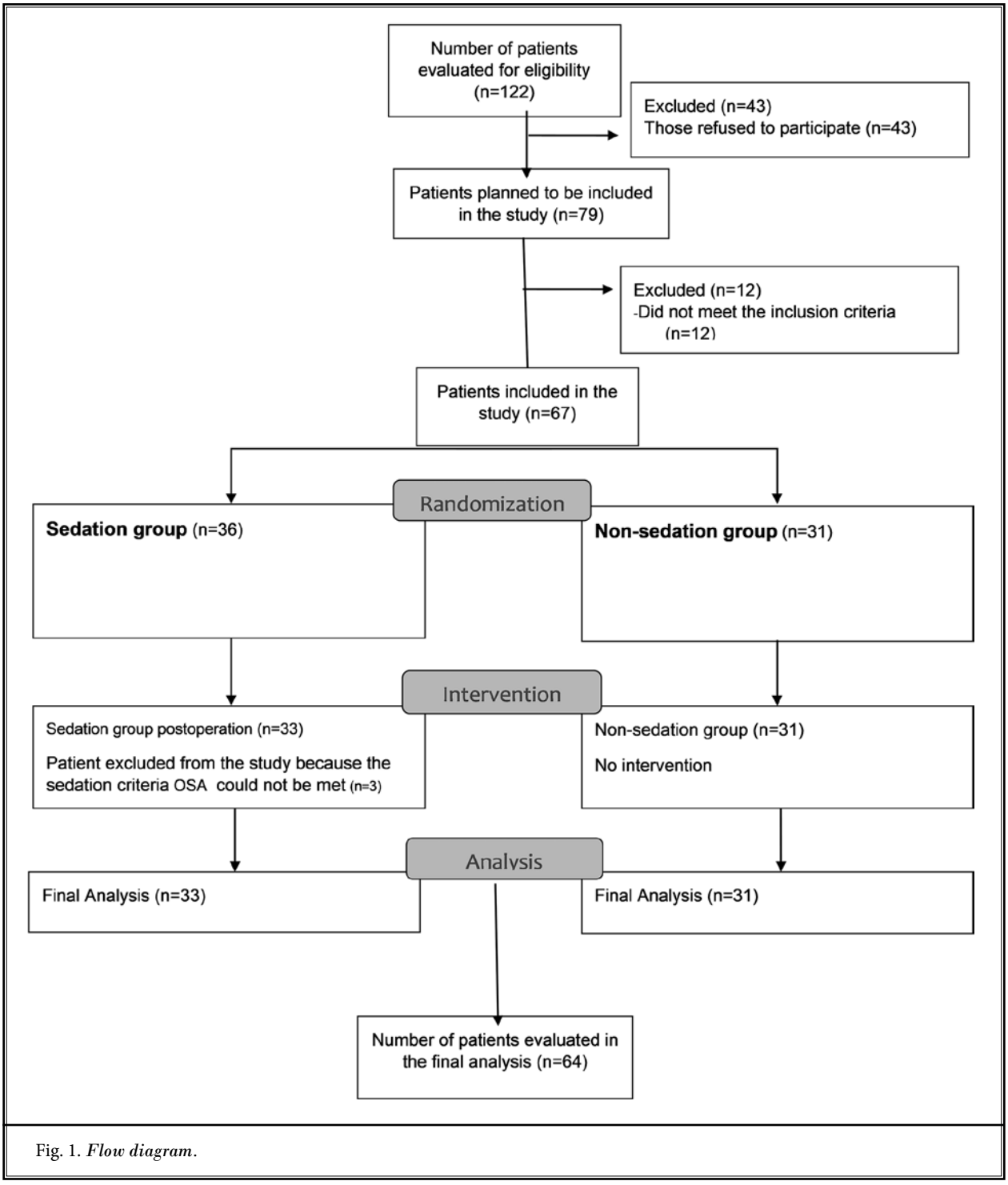

Fig. 1. *Flow diagram.*

be required because the number of possible drop-outs was expected to be high.

Results

One hundred and twenty-two patients were included in the evaluation. As a result of the exclusion cri-

teria, 67 patients were included in the analysis, out of which 3 patients were excluded from the study because the OSA {sp} criteria for those patients could not be met, and a total of 64 patients were included in the final analysis (Fig. 1). Single-level single-root TFESI was performed on a total of 64 patients, with 33 (51.4%) in the sedation group and 31 (48.4%) in the nonsedation group.The demographic and clinical data of all patients are given in Table 1.

When the sedation group and the nonsedation group were compared, no significant difference was found in terms of the demographic data ($P > 0.05$) (Table 2). In the comparison of HADS depression and anxiety scores and NRS-11 scores between the groups, they were found to be similar in the preprocedural period ($P > 0.05$). The periprocedural NRS-11 scores were significantly higher in the nonsedation group ($P < 0.0001$). However, it was found that this significance was not reflected at the second hour NRS-11 scores ($P > 0.05$). Again, in the comparison between the groups, it was found that both the patient satisfaction and the physician satisfaction were significantly higher in the sedation group ($P < 0.0001$). When we asked our patients if they would like to undergo the intervention with the same technique in the case of repetition of the intervention, 87.87% of the sedation group redemanded sedation, whereas only 38.72% of the nonsedation group redemanded to have the intervention without sedation. As a result, there was a significant difference between the 2 groups in terms of the redemand for undergoing the same intervention with the same technique ($P < 0.0001$) (Table 2)

When the correlations of the current data of the groups were analyzed by regression analysis, we reported that there was a significant correlation between the NRS-11 intervention values (odds ratio [OR], 0.341; $P = 0.0001$), redemand to have the intervention with the same technique (OR, 0.648; $P = 0.0001$), and being in the sedation group (Table 3). Likewise, we found a significant correlation between the patient satisfaction (OR, 0.329; $P = 0.0001$) and physician satisfaction (OR, 0.514; $P = 0.0001$) and being in the sedation group.

When the periprocedural and postprocedural second hour complications of the patients who participated in our study were evaluated, in the sedation group, it was found that 2 patients developed dizziness and one patient developed itching. In the nonsedation group, 2 patients cried and were agitated, and one patient developed hypertension. There was no statistical difference in terms of the number of complications.

Table 1. *Demographic and clinical data.*

Age (years)	44.93 ± 10.51
Gender Male Female	 37 57.89% 27 42.2%
BMI	44.93 ± 10.51
HADS depression	5.50 ± 3.94
HADS anxiety	6.42 ± 4.027
Preprocedural NRS-11	7.68 ± 1.03

BMI, body mass index.

Table 2. *Comparisons between the groups.*

	Sedation n = 33 (51.6%)	**Nonsedation n = 31 (48.4%)**	***P* value**
Age (years)	44.87 ± 9.86	45.01 ± 11.33	0.964
Gender Male Female	 22 (66%) 11 (33.3%)	 15 (48.3%) 16 (51.7%)	 0.205
BMI	27.99 ± 4.12	29.58 ± 4.91	0.168
HADS depression	6.01 ± 4.68	5.06 ± 3.48	0.371
HADS anxiety	6.88 ± 4.96	5.97 ± 3.35	0.396
Preprocedural NRS-11	7.78 ± 0.99	7.58 ± 1.08	0.429
Periprocedural NRS-11	1.06 ± 1.27	3.94 ± 1.93	0.0001*
Second hour NRS-11	1.58 ± 1.17	2.06 ± 1.26	0.114
Patient satisfaction	4.63 ± 0.82	2.48 ± 1.31	0.0001*
Physician satisfaction	4.75 ± 0.61	2.67 ± 1.13	0.0001*
Redemand for intervention Yes No	 29 (87.87%) 4 (12.13%)	 12 (38.7%) 19 (61.3%)	 0.0001*

$P < 0.05$ was considered significant.
BMI, body mass index.

Discussion

In our study, we aimed to investigate the importance of sedation administered with lumbar TFESI in terms of patient and physician satisfaction. The results we recorded suggest that 1) the patients who received sedation had less pain during the intervention; 2) the patient and physician satisfaction was higher; and 3) patients would prefer the same technique if intervention would need to be performed again.

In the literature, we found that the number of prospective randomized studies evaluating the correlation between TFESI and sedation was limited as far as we could

Table 3. *Multiple regression analysis.*

			95% CI for EXP (B)	
	Odds Ratio	Significance	Lower	Upper
Periprocedural NRS-11	0.388	0.0001	2.344	10.787
Patient satisfaction	0.329	0.0001	0.122	0.445
Physician satisfaction	0.514	0.0001	0.038	0.287
Redemand for intervention	0.648	0.0001	3.221	40.912

CI, confidence interval.

determine (8-10). Therefore, we believe that our study will contribute positively to the literature as there are a limited number of studies in this respect. A retrospective study conducted in a radiology department in 2013 compared 4,432 patients in the sedation group with only 7 patients in the nonsedation group but could not provide a statistical result because the number of patients in the sedation group did not allow any comparison (9). Moreover, there is a heterogeneous study group in which lumbar, cervical, and thoracic region TFESI procedures were performed under the guidance of computed tomography or fluoroscopy, and one to 4 or more procedure repetitions were administered to the patients (9). However, unlike our result, they suggested that the nonsedation group had a higher patient satisfaction (9). We are of the opinion that the reliability of a retrospective study with a nonhomogeneous study group and without statistical comparison is low.

In a study conducted to measure the anxiety levels of patients prior to a spinal injection, lumbar, thoracic, and cervical injections were collectively analyzed, and it was suggested that patients did not routinely require sedation (11). However, their first problem requiring consideration is that 1) the patients were not informed that they could request routine sedation, and 2) sedation was administered only to those who specifically requested it. We are of the opinion that the results could be very different if this option had been offered to the patients. Although 17% of their patients demanded sedation for the first intervention, this demand has increased to 28% for the second intervention, which is remarkable and corresponds to almost one-third of the patients (11). In the questionnaire survey by Kim et al (10) including 300 patients, patients who were scheduled to undergo lumbar and cervical epidural intervention were evaluated. A total of 58% of the patients preferred sedation and 90% of these found sedation effective. The satisfaction of the patients who received sedation was parallel to our study.

In our study, we used the modified MOAA/S scale to obtain the sedation depth, which was the 5-level version of the MOAA/S scale that included only the "respond" part (12-14). The recent review by Williams et al (12) reveals the efficacy and validation of the MOAA/S scale. Aydemir et al (7) performed the validation study of the HADS depression/anxiety tests for Turkish people. The fact that there was no difference between the groups in our study in terms of pain, depression, and anxiety scores during the preprocedural period forms a good basis for the consistency of our evaluations.

In a recent questionnaire, the opinions of the member physicians from the American Society of Regional Anesthesia and Pain Medicine and the American Academy of Pain Medicine were obtained, and 54% of the physicians reported that they used sedation during epidural steroid injection (15). Of the physicians, 97% preferred benzodiazepines and 77% preferred opioids as the agents they used most commonly (15). In our study, we also preferred benzodiazepine + opioid combination; thus, we combined the anxiolytic and analgesic effects. Benzodiazepines (midazolam) are widely preferred in sedation during interventions because they have a rapid onset of action (30-60 seconds). For these reasons, they are very effective in short operations (16,17).

One of the major problems we faced in this study was the provision of sedation depth. As indicated by Ward et al (18) in their review, both inadequate and excessive sedation during interventional procedures may cause problems during procedures (19). The review also indicated that inadequate sedation may result in patient dissatisfaction, and may even prevent the procedure from being completed. We attempted to avoid this by administering additional doses to the patients with inadequate sedation (18). However, 3 of our patients developed excessive sedation, so we had to exclude them from the study.

An author has suggested that avoidance of sedation reduces costs, difficulties, intervention safety, and complications (9). However, we think that avoidance of sedation means that patient and physician satisfaction are also affected. Furthermore, very few complications have been reported in patients with conscious sedation in the literature (20). Therefore, we believe that the safety of intervention will significantly improve in cases in which patient's desire to move owing to his or her anxiety

reduces and physician concentrates more on his or her work. Although extra time required for the administration of sedation results in prolonged procedural time, in our study, is does not affect the physician satisfaction. We are aware that measurement of time in the procedural room could be longer for patients given sedation that can impact staffing needs and room turnover. Also, time of patient to discharge from the hospital can prolong after the procedure, but we think that the importance of a 2-hour waiting period should be carefully evaluated when comparing with the importance of patient satisfaction.

In terms of procedure safety, it is very important that patients who receive moderate sedation are able to report their paresthesia or pain complaint arising in the case of inadvertent spinal nerve or root contact during the procedure. We are of the opinion that other centers using conscious sedation work with similar security levels. Hodges et al (21) detected permanent neurologic injury with sedation in 2 case reports of cervical epidural steroid injection, and they reported and suggested that no sedation should be used in these patient groups (11). However, we think that what is worth noting here is the level of sedation rather than its presence. Because, in this publication, they reported that 2 mg of midazolam and 50-55 mg of propofol were administered to those 2 patients with nonspecified sedation level, and it is obvious that propofol administrations at such dose would probably result in deep sedation and even general anesthesia for those patients. We are of the opinion that it is not possible to expect any response from a patient at such a high level of sedation. Our recommendation is to prefer mild and moderate (conscious) sedation, which will increase the patient and physician satisfaction, and in which the patient can easily alert us when the likelihood of any complication is determined.

Our study also has limitations. The pain assessment shows individual differences for patients and was performed using the NRS-11, which is a subjective measurement method. However, the NRS-11 is still widely used for pain assessment because more objective assessment methods are not yet available in the literature. Another limitation of our study is the possible differences in the herniation sizes and degeneration rates of the patients' current pathologies. However, we tried to prevent that by randomizing the patients. In our study, both patients and physicians were unblinded, therefore, placebo effect cannot be excluded.

Conclusions

The coadministration of lumbar TFESI with sedation decreases the intraoperative pain values and results in patient demand to have the procedure with sedation, if the intervention is repeated. If the sedation depth is adjusted properly, lumbar TFESI can be administered safely with sedation, and also it provides an important advantage in terms of increasing the patient and physician satisfaction.

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